



EOL Care Companion II

Grant Number: R44CA097592-03

Abbreviated Abstract

The U.S. health care system depends on an estimated 52 million informal caregivers to provide care to ill or disabled adults in their homes. Most of these caregivers are family or friends, not paid assistants or volunteers. Increasingly, they are caring for the seriously ill and those with progressive life-threatening illness. As life expectancy rises, death comes after years of chronic disease and the numbers of those “living with dying” grows. Family and friends are called upon to act as caregivers, advocates, and proxies for loved ones who are approaching the end of life. To meet these challenges, family caregivers need information for decision making, skills education to manage the many tasks involved in providing end-of-life care, and emotional support.

Care Companion will offer an integrated service consisting of standalone and “live” components, including 1) interactive multimedia resource that provides professionally reviewed information on end-of-life and skills training deliverable on CD ROM or online; 2) a comprehensive online service that provides the CD ROM / online content parsed for customized access (via registered user profiles), user-generated content (from online events and user contributions), and peer-to-peer interaction and sociability. This integrated customized education and support environment is based on the following assumptions: 1) better-informed family members will be better caregivers, 2) learning is enhanced as part of a social process, 3) the combination of education and support will enhance the care giving experience and reduce its negative effects on caregivers. By supporting family caregivers we hope to improve the quality of end-of-life care for care receivers and their families.

The combination of online education and peer support will be scientifically evaluated using a randomized controlled trial to examine the effectiveness of Care Companion in reducing the adverse effects of care giving. Effects on caregivers will include self-report of their physical and mental well health (SF 12) and their emotional response to their situation (perceived stress, coping, perceived self-competency and loneliness).

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Research Team & Affiliations

Talaria Inc:

- Leif O’Leary, Graphic designer and media production specialist
- Glenda Polwarth, Chief Technology Officer
- Susan Stoner, PhD, Psychology - research design and data analysis



- Nelli Tkach, Research Assistant
- Eileen Van Schaik, PhD, Principal Investigator

The NewSof Group:

- Dan Newton, PhD, NSG President (until January 1, 2008)
- Neal Sofian, MPH, NSG CEO (until January 1, 2008)

Enclara Health:

- Ruth Egan, Quality Assurance
- Kristen Hodel, Marketing & Communication Manager
- Gail Hudson, Community Manager (Enclara employee effective 08-01-2008)
- Kathleen Sidenblad, VP of Engineering (until July 18, 2008)

Consultants:

- Doug Brock, PhD, Medical Education and Informatics, University of Washington
- Elisabeth Cuddihy with Judith Ramey, Director, Laboratory for Usability Testing and Evaluation, University of Washington
- Laurie Fronek, Writer
- Gail Hudson, Managing Editor (08-01-2006 – 07-31-2008)
- Kathleen Klein, Instructional Design and Usability
- Cheryl Slean, Writer and audio producer
- Helene Starks, PhD, MPH, Medical History & Ethics, University of Washington – end-of-life care and caregivers

Total Budget

\$1,326,220

Research Objectives

AIMS:

- Expand the resource developed in Phase I to provide a more comprehensive web service that meets a broader set of user needs and is attractive to health care delivery systems, health insurers, long-term care facilities, hospice organizations, and patient information and advocacy groups.
- Scientifically evaluate the combination of online education and peer support, using a randomized controlled trial to examine the effectiveness of Care Companion in reducing the adverse effects of care giving. Effects on caregivers will include self-report of their physical and mental well health (SF 12) and their emotional response to their situation (perceived stress, coping, perceived self-competency, and loneliness).

Theory/Hypothesis

Primary Hypothesis:

- 1) The Care Companion intervention will reduce the negative effects of care giving on the physical and mental health of caregivers as measured by the SF 8.

Secondary Hypotheses:

- 1) The Care Companion intervention will reduce the negative effects of care giving on caregivers as measured by improved scores in one or more of the following measures: Stanford Presenteeism Scale (SPS), Caregiver Reaction Assessment (CRA) and Skills Mastery, Mental Health Status Measure (PHQ-8), and Perceived Stress Scale (PSS)



- 2) There will be a trend for greater improvement in Caregiver Reaction Assessment (CRA) and Skills Mastery, Mental Health Status Measure (PHQ-8), and Perceived Stress Scale (PSS) scores among caregivers with higher rates of participation in the online community.
- 3) The Care Companion intervention will promote behavioral change and personal growth in keeping with caregivers' personal goals.
- 4) The Care Companion intervention will receive high ratings of satisfaction and perceived value by caregivers.

Experimental Design

Effectiveness trial: separate-samples pretest post-test quasis-experimental design with intent-to-treat

Final Sample Size & Study Demographics

Inclusion criteria: To be eligible for the study, caregivers must:

- be at least 18 years of age,
- be providing care in the home to persons with a life-threatening progressive illness and considering issues that will arise with end-of-life care,
- speak English as their primary language,
- have access to a computer with Internet capabilities, and
- agree to participate in the baseline and three month data collection.

There are no criteria for exclusion once potential participants meet these requirements.

To achieve 80% power with $\alpha=.05$ with a two-sided t-test we need a total of 352 subjects (176 in each group). Assuming a 20% loss to follow up, we will need to recruit a total of 440 subjects.

Data collection is ongoing. To date we have 69 enrolled participants of whom 65 have completed the baseline questionnaire, 26 have received their 3-month reminder and 13 who completed the 3-month questionnaire.

Data Collection Methods

Data collection takes place online. Everyone who registers as a member in CareCommunity is sent an email invitation to join the study. A link in the email takes them to the study website on Talaria Inc.'s server. Here they are screened for eligibility, read and accept an Information Statement, and enroll in the study. Participants are encouraged to complete the questionnaire in one sitting if possible, but they are able to save & quit and then return as many times as needed. In addition, participants are asked to indicate their willingness to participate in a phone call when the study is completed. At that point we will randomly select 10 percent of study participants ($n=44$) for a follow-up phone discussion about their caregiving experiences and the role that peer support via the online community may have played.

Outcome Measures

Baseline	Three-month Follow-up
Web Proficiency	-
Demographics	-
Employment Status	Employment Status
Stanford Presenteeism Scale (SPS)	Stanford Presenteeism Scale (SPS)
Care Giving Experience	-
Care recipient's functional status: Activities of Daily Living (ADL)	Care recipient's functional status: Activities of Daily Living (ADL)



Baseline	Three-month Follow-up
Instrumental Activities of Daily Living Scale (IADL)	Instrumental Activities of Daily Living (IADL)
Caregiver Reaction Assessment (CRA) and Skills Mastery	Caregiver Reaction Assessment (CRA) and Skills Mastery
Health Status Measure (SF-8)	Health Status Measure (SF-8)
Mental Health Status Measure (PHQ-8)	Mental Health Status Measure (PHQ-8)
Perceived Stress Scale (PSS)	Perceived Stress Scale (PSS)
-	New Behaviors and Personal Growth
-	User Satisfaction
-	Evaluation of Your Experience with Care Community

Evaluation Methods

- Analyses of study aims: Our trial utilizes a separate-samples pretest post-test design with intent-to-treat. Participants are randomized into either an experimental or a control group at pretest. The pretest of the control group will be compared to the post-test of the experimental group. Intent-to-treat refers to the inclusion of all randomized participants in hypothesis testing, regardless of how much participants used the website. Independent-groups t-tests will be used to test primary and secondary hypotheses.
- Analysis of effects of patient variables: secondary analyses will examine the effects of the intervention on the relationships among the outcome measures. Further secondary analysis will assess possible effects of subject covariates on the outcome measures.
- Behavioral change and personal growth: there are no hypotheses to test for behavioral change and personal growth. The analysis will focus on summarizing caregivers' self report and assessing them in relationship to demographic variables, caregiver experience, and utilization and participation metrics.
- Usability and usage analyses: These analyses will focus on summarizing these measures and assessing the relationships between demographic variables and the usability and usage measurements. We will examine whether satisfaction and usefulness increase as a function of usage.

Research Results

Data analysis for the outcome evaluation is pending. Below are previews of study participant demographics and user activity on the site.

Study demographics

- Our biggest question as we developed the site was the age of the users we would attract. Of the 69 study participants, 49 are 40 to 64 years old, there are 5 in the 35 – 39 category and a total of 9 in the over 64 category, with 1 in the 80 – 84 range. To date we have only 4 in the 25 – 34 range.
- Another major concern was to develop a site that attracted racial/ethnic minorities. Of 69 participants selecting as many categories as they wished, 61 identify as white, 3 as Hispanic, 4 as Black, 5 as Asian American, 6 as Native American, 3 as Hawaiian, and 2 as other.
- The gender differences among participants are dramatic with only 6 male participants and 63 female, suggesting a need to develop a strategy for recruiting male caregivers.

Activity on CareCommunity

Activity on the site by registered members is being logged for analysis. In addition, we are using Google Analytics for immediate snap shots of users' activities. During the current, community-building phase, the Community Manager and Enclara's palliative care experts are contributing in various site forums to seed discussions. To date we have approximately 157 postings by non-staff members of the community to Ask an Expert, Discussion Forums, caregiver stories, and blogs. At least 271 users created a Private Care Page between April 1 and August 31, 2008.



Leading topics and functions, based on page visits are as follows:

- 1) Caring for Others: Content to help caregivers provide better care to others
- 2) Home Personal Profile Page : Page people go to after registering to create a profile and later return to when updating profile
- 3) Finding Resources: Quick link button goes to hospice locator and search tool for the CareCommunity site, as well as the internet
- 4) People Search – Find People Like Me: unique search to find others who match your demographics or caregiving situation
- 5) Caring For You: Content to support caregivers
- 6) Search for Information: clicking on search tool at top of page – offers Internet search and CareCommunity search
- 7) Making Decisions – helps people with all matters of advance planning, choosing palliative care or hospice and financial decision making
- 8) Discussion Forum – Highly interactive with broader CareCommunity-opportunities to post questions and comments with other caregivers.
- 9) Stories and Advice – Personal stories and advice posted by caregivers to other caregivers with comments allowed.
- 10) FAQs – How to navigate the site
- 11) Blogs – personal blogs by caregivers for public viewing (with an option for private view only settings)
- 12) Looking Ahead – Content for end-of-life care and managing grief
- 13) Ask an Expert – post question to a team of experts
- 14) Personal Start Page – The page you automatically go to after you sign in.

Barriers & Solutions

- 1) Obtaining information from target users for site design and usability: the majority of caregivers are over 65 and the fastest growing segment of internet users are over 65, but we wouldn't know until we had user data for our site, who are users would be. It was difficult to access and recruit caregivers for focus groups. Service providers, such as hospices, are protective of caregivers and caregivers are extremely busy and often unable to leave their homes. We supplemented a limited number of focus groups with consultations with individual caregivers and service providers. Additionally, the development team differed on who to target and how to design the site. These differences were largely resolved by usability studies with caregivers conducted locally and at the NCI usability lab. Finally, to compensate for the lack of minority caregivers in focus groups and usability testing, we consulted with the Seattle-based African American Comfort Program who provided recommendations and two caregivers who joined the community and contributed to the site. Expert articles provided by NHPCO have been translated into Spanish for the site.
- 2) Multiple stake-holders: Enclara Health became a client for the site before funding began and their long-term interests in the site had to be considered throughout development and the study. While this complicated some aspects of the project, particularly the research design for the study, they are supportive of the Specific Aims of the grant and contribute expertise and material support for the project. Additionally, the web site was developed by the NewSof group in collaboration with Talaria Inc (who holds the grant). NewSof oversaw development but contracted iLink for the programming work. At the same time, Talaria took the lead in content development and contracted a team of professional writers to interview experts and write original material for the site. With so many parties involved, changes in personnel were inevitable. NewSof withdrew from the project after 16 months to pursue other interests and Enclara assumed responsibility for supervision and payment of iLink. However, after two years, Enclara's VP of engineering, who had led the collaboration from their side, resigned and the recently hired Marketing & Communications Manager assumed that responsibility. Coordination of all these teams has been the PI's responsibility and has been possible because everyone supports the Specific Aims for the grant and shares a commitment to improving end-of-life care and supporting caregivers. The Talaria and NewSof teams met weekly for the first 18 months and Enclara joined in



periodic conference calls with occasional visits to Seattle for meetings. We met our content development and site development goals for year 1 of the project, but were significantly delayed in year 2 by a cumbersome and time-consuming process for moving the site from iLink's development environment to Enclara's production environment with testing on both sites. A one-year no-cost extension from the NCI was necessary to allow sufficient time to conduct the evaluation study.

- 3) Research Design: With Enclara Health building its customer base among hospices and insurance providers, it became untenable to recruit end-of-life caregivers for the outcome evaluation from the website and then randomize participants to a control group that would not receive the intervention, i.e., access to the Care Community website. After many meetings when the needs of caregivers, Enclara, and scientific research were considered, we modified our research design to an effectiveness trial using a separate-samples pre-post design comparing baseline measures from a randomly assigned control group that receives the intervention to post-test measures from a randomly assigned experimental group. This will minimize maturation bias inherent to a single group pre-post design and enables us to avoid denying the intervention to any caregivers.
- 4) Building the community and study recruitment: Our ongoing challenge is recruiting caregivers to join the community and enroll in the study. Through Enclara, we are partnering with numerous entities (listed below) for recruitment on their website and by their providers. We are also working with iLink to maximize traffic to the site and at the end of February 2008, we began marketing the site via Google AdWords and the Google search engine. Since the accounts began, the implementation team has taken CareCommunity from a #70 general search ranking to #10. Enclara has sent out press releases and has printed attractive brochures for site which are distributed at industry conferences (listed below). Talaria has assigned a RA (with current family caregiving experience) to follow caregiving stories on the web and to post comments about the site wherever appropriate. Everyone involved in the project has sent invitations to the site to their personal and professional networks. To date we have over 1,098 registered members in CareCommunity.

Product(s) Developed from This Research

[CareCommunity.org](http://carecommunity.org)